

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION**

UNITED STATES OF AMERICA *ex rel.*

Richard Lardner,

Plaintiff-Relator,

VS.

SMITH & NEPHEW, INC., and  
METRO MEDICAL EQUIPMENT  
& SUPPLY, INC.,

Defendants.

Civil Action No. **2:17-cv-01013-JPM-egb**

**SMITH & NEPHEW, INC.'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS**

In its motion to dismiss, Defendant Smith & Nephew, Inc. (“Smith & Nephew”) showed that Relator’s Complaint failed to meet the False Claims Act’s “stringent” pleading requirements and should be dismissed with prejudice. Dkt. 18. Apart from its other flaws, the Complaint is plainly defective because it neither (1) pled particularized details of a scheme to defraud the Government, or (2) identified specific examples of “false claims” presented to the Government.

In response, Relator *concedes* that he cannot meet those “indispensable” pleading requirements. Dkt. 37 at 16. Instead, Relator asks the Court to create an exception to the applicable pleading standard because the alleged scheme was “targeted” at Government purchasers. *Id.* at 7. That unprecedented exception, however, would violate decades of Sixth Circuit precedent recognizing that the FCA’s heightened pleading standard can be relaxed only if a relator has specific personal knowledge about the defendant’s billing practices or government contracts.

Here, Relator lacks any personal knowledge about critical aspects of the alleged scheme. Nor can he identify with specificity any false claims (or statements) presented to the Government. The Court should reject Relator’s attempt to substitute baseless speculation for the particularized pleading standard that applies in this context. The Complaint should be dismissed with prejudice.

#### **I. The Court Should Decline To Relax The Applicable Pleading Standard**

Despite Relator’s citations to inapplicable case law, the pleading standard for FCA complaints in this circuit is well-settled. To plead an actionable claim, a relator must both (1) satisfy the False Claims Act’s specific elements, and (2) meet the heightened pleading standard of Rule 9(b). *U.S. ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 880-81 (6th Cir. 2017). Where, as here, the relator attempts to meet that burden by alleging a “complex and far-reaching fraudulent scheme[,] . . . it is insufficient to simply plead the scheme; [relator] must also identify a representative false claim that was actually submitted to the government.” *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017); *Hirt*, 846 F.3d 881 (“The

identification of at least one false claim with specificity is ‘an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b).’”).

Recognizing his inability to meet that requirement, Relator asks the Court to relax it on the grounds that he has alleged “facts which support a strong inference that a claim was submitted.” Dkt. 37 at 7-8. In effect, Relator is asking the Court to adopt a new pleading standard under which FCA relators need only allege facts that (1) indicate the submission of false claims “follows closely from the details of the scheme,” and (2) put Defendants “on notice” of the alleged fraud. Dkt 37 at 6, 8. The Court should decline to adopt that new rule.

Contrary to Relator’s assertions, the Sixth Circuit has “‘relax[ed]’ [Rule 9(b)’s particularity] standard just once” in an FCA case. *Hirt*, 846 F.3d 881 (citing *U.S. ex rel. Prather v. Brookdale Senior Living Comtys., Inc.*, 838 F.3d 750, 769 (6th Cir. 2016)). In that case, the court held that the relator’s “allegations satisfied the particularity requirement because she had sufficient personal knowledge of the defendant’s claims submission and billing processes.” *Hirt*, 846 F.3d 881. In subsequent cases, the court has clarified that the “limited” *Prather* exception “applies only if ‘a relator alleges specific personal knowledge that relates directly to billing practices,’ supporting a ‘strong inference that a [false] claim was submitted.’” *Ibanez*, 874 F.3d at 915. Indeed, the Sixth Circuit has repeatedly rejected attempts to expand the exception when a relator lacks personal knowledge about the defendant’s billing practices or government contracts. *Hirt*, 846 F.3d 882 (rejecting exception when relator did “not allege personal knowledge of [defendant’s] claim submission procedures”); *Ibanez*, 874 F.3d at 916 (rejecting exception when the relator lacked specific knowledge of the defendant’s billing practices); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 471–72 (6th Cir. 2011) (declining to apply exception when the relator “lack[ed] . . . personal knowledge of billing practices or contracts with the government”).

Relator also attempts to excuse his pleading deficiencies by recasting his allegations as a “fraudulent inducement” claim. Dkt. 37 at 8; *see In re Plavix*, 2017 WL 2780744, at \*6 (D. N.J. June 27, 2017) (describing “fraud-in-the-inducement” as a “narrow category” of FCA liability covering all claims submitted to the government under a contract which was procured by fraud, even though the resulting claims were not themselves false). But even if Relator’s muddled allegations are read to state a fraudulent inducement theory, he still would have needed to allege the underlying fraud with particularity—including details about the “false statements” that allegedly induced the Government to enter into specific contracts. *U.S. ex rel. New Mexico v. Deming Hosp. Corp.*, 992 F. Supp. 2d 1137, 1154 (D. N.M. 2013) (recognizing that the “essential elements” of a “false certification theory” and a “fraud-in-the-inducement” theory “remain the same”); *U.S. ex rel. Dekort v. Integrated Coast Guard Sys.*, 705 F. Supp. 2d 519, 537-38 (N.D. Tex. 2010) (dismissing FCA fraudulent inducement claim because it “‘d[id] not allege who was involved in the contract negotiations, or where and when the negotiations took place’ and ‘[t]here are no facts alleged as to what was said before, during, or after the contract negotiations’”).

Here, Relator lacks personal knowledge that would justify relaxing the particularity requirement and has failed to identify with specificity any false claims (or statements by Defendants that induced the Government to sign a contract). For instance, Relator never worked at Metro Medical—the entity that actually contracted with (and submitted claims to) the Government. Thus, Relator has *no information* about (1) Metro Medical’s government contracts, (2) any statements made to procure those contracts, or (3) any claims for payment submitted under those contracts. Nor does Relator know anything about how Metro Medical distributed any relevant products or about its contracts with Smith & Nephew—its alleged co-conspirator. Instead, Relator merely offers (1) speculation about events that happened after he left his job at Smith &

Nephew, Dkt. 3 ¶ 97, and (2) summary information about Metro Medical’s government contracts that he pulled from the internet. *Id.* ¶ 99-100 Under these circumstances, the Court should not relax Rule 9(b)’s “indispensable” pleading requirements.<sup>1</sup> Rather than create a new exception that excuses Relator from Rule 9(b)’s heightened pleading standard, the Court should instead recognize that Relator “was not the right plaintiff to bring this qui tam claim.” *Hirt*, 846 F.3d 882.

## **II. Relator’s Allegations Lack Particularity And Plausibility**

Plaintiff’s Complaint alleges that Defendants conspired to execute two schemes to fraudulently procure federal contracts. In the first scheme, Smith & Nephew allegedly used Metro Medical as “sham small business distributor” to procure federal contracts set aside for small businesses. In the second scheme, Smith & Nephew allegedly caused Metro Medical to misrepresent that certain products were made in the United States in order to obtain government contracts reserved for American-made products.

Smith & Nephew’s motion to dismiss showed that both scheme allegations should be dismissed for failing to satisfy Rule 9(b)’s particularity requirement and basic 12(b)(6) plausibility standards. In response, Relator attempts to avoid dismissal by mischaracterizing applicable regulations and introducing new “facts” to fill holes in his Complaint. Neither tactic, however, can overcome the Complaint’s defects. The Complaint should be dismissed with prejudice.

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<sup>1</sup> Relator also wrongly argues that Rule 9(b) merely requires plaintiffs to provide enough detail to allow defendants to draft a responsive pleading. Dkt. 37 at 8. To the contrary, the Sixth Circuit has expressly rejected Relator’s argument that notice pleading is sufficient in the FCA context. *Chesbrough*, 655 F.3d at 472 (rejecting argument that an FCA complaint would be sufficient if it “alerted [defendant] to ‘exactly what the fraud entails’”); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 503 n.11 (6th Cir. 2007) (holding that Rule 9(b) “prevents prospective plaintiffs from engaging in fishing expeditions to uncover moral wrongs, and protects defendants’ reputations against damage stemming from accusations of immoral conduct”).

### A. Relator's Sham Distributor Allegation Lacks Particularity and Plausibility

To plead an actionable scheme under the False Claims Act, Relator must (1) describe the scheme “with particularity” and “in detail,” *United States ex rel. Eberhard v. Physicians Choice Lab. Servs. LLC*, 642 F. App'x 547, 550 (6th Cir. 2016), and (2) plead “particularized allegations of an actual false claim” presented to the Government under that scheme. *Bledsoe*, 501 F.3d at 505. In addition, Relator's allegations must cover “the entire chain” of “causal links” from “defendants' conduct to the eventual submission of claims” in order to “fairly show defendants caused false claims to be filed.” *Ibanez*, 874 F.3d at 914.

Relator's response “primar[ily]” argues that his sham distributor allegation is actionable because he has adequately pled that Smith & Nephew and Metro Medical are “affiliates”—which would mean that Metro Medical was ineligible for federal contracts “set aside” for small businesses. Dkt. 37 at 10-13. Under the applicable regulations, Metro Medical would be an “affiliate of” Smith & Nephew if the latter “controls or has the power to control” Metro Medical. 13 C.F.R. § 121.103(a)(1). To determine whether Smith & Nephew “controls” Metro Medical, the Government would consider factors “such as ownership, management, previous relationships with or ties to another concern, and contractual relationships.” 13 C.F.R. § 121.103(a)(2).

Recognizing that he lacks any information about the applicable “control” factors, Relator's Complaint has tried to rewrite them. Relator does not argue that Smith & Nephew has the power to *control Metro Medical*, which could include the contractual right to force Metro Medical to do something, or the power to block Metro Medical from taking some action. 13 C.F.R. § 121.103(a)(3) (“Control may be affirmative or negative. Negative control includes, . . . the ability . . . to . . . block action by the board of directors or shareholders”). Instead, Relator claims that Smith & Nephew improperly “*control[led] transactions*” with the Government by taking “the primary role in selling the product[s]” to VA hospitals. Dkt. 3 ¶ 110; Dkt. 37 at 12.

However, despite his attempt to save the Complaint by rewriting regulations, Relator's sham distributor allegation fails for three reasons. First, Relator has not specifically identified a false claim that was submitted to the Government under the alleged scheme (or a false statement that induced the government to enter a specific contract). *Hirt*, 846 F.3d at 881 (holding that identifying a false claim "with specificity" is an "indispensable element" of an FCA complaint"). While the Complaint does allege facts about a "quote" for an August 2011 contract that was submitted by Metro Medical in 2010, the Complaint does not allege any facts about the negotiation, solicitation, or fulfillment of the August 2011 contract. Dkt. 3 ¶¶ 88-97. Indeed, Plaintiff could not possibly allege any facts about the fulfillment of the August 2011 contract because his employment at Smith & Nephew ended in January 2011. Dkt. 3 ¶ 15. Without that information, Relator has not alleged particularized details about a specific false claim or fraudulent statement to the Government. *Ibanez*, 874 F.3d at 914 (FCA complaints must allege details about the "entire chain" of "causal links" from a defendant's conduct to the submission of a specific false claim).

Second, even if Relator did not have to identify a specific false claim, his sham distributor allegation separately fails because he has not pled facts that could establish "control" under the applicable regulations. The fact that Smith & Nephew allegedly marketed products to VA hospitals that were later distributed by Metro Medical does not mean that Smith & Nephew has the power to "control" Metro Medical. 13 C.F.R. § 121.103(a)(2) (listing relevant control factors, "such as ownership, management, previous relationships with or ties to another concern, and contractual relationships"). Relator's proposed rule for assessing control—*i.e.*, does a manufacturer have the "primary role" in the transaction—would overturn decades of regulatory authority affirming that small business nonmanufacturers can act as drop shippers. *Size App. of: Wear Mark, Inc., Re: A2z Promo Zone*, SBA No. SIZ-5397, 2012 WL 4359132 (S.B.A. Sept. 12,

2012) (“Small business nonmanufacturers therefore have a long history of drop shipping,[,] [and] the Small Business Act does not prohibit drop shipping, and OHA has permitted it.”). None of that authority has required small business nonmanufacturers to negotiate price terms or have “the primary role” in the transaction. *Id.* Relator has failed to plead any facts suggesting that Smith & Nephew has the power to force Metro Medical to do anything (or that Metro Medical is somehow economically dependent on Smith & Nephew). The Court should not condone Relator’s attempt to rewrite regulations in order to compensate for his lack of relevant information.

Third, Relator’s sham distributor claim fails because he has not alleged that Smith & Nephew’s involvement with the disputed contracts was “material to the Government’s payment decision.” *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). The FCA’s materiality standard is “rigorous” and “demanding” and can be the basis for dismissing an FCA case at the pleading stage. *Id.* at 2002-03, 2004 & n.6. A regulatory violation is not “material to the Government’s payment decision” when “the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated.” *Id.* at 2003.

Here, Relator has failed to sufficiently allege materiality because his entire claim is premised on the fact that the Government had full knowledge of Smith & Nephew’s involvement with the disputed transactions. Indeed, when claiming that Smith & Nephew “controlled” all aspects of the disputed transactions, Relator specifically alleges that Smith & Nephew had “all on site and direct interactions with [government purchasers]” relating to the “pricing, sale, delivery and set up of TRUCLEAR systems.” Dkt. 3 ¶ 76. The fact that the Government paid for the disputed products, despite its full knowledge of Smith & Nephew’s involvement, shows that any hypothetical regulatory violations were immaterial to payment. *Escobar*, 136 S. Ct. at 1996.



Relator cannot have it both ways by claiming, on the one hand, that Smith & Nephew exclusively interfaced with the Government, while, on the other, that the Government would not have paid for products if it knew about Smith & Nephew's involvement. Unless Relator can allege the Government was ignorant of some material aspect of the alleged scheme, Relator's sham distributor allegations should plainly be dismissed with prejudice. *Escobar*, 136 S. Ct. at 1996.

**B. Relator's Sham Small Business Nonmanufacturer Allegation Should Be Dismissed**

Relator's Complaint separately alleges that Metro Medical was not eligible for federal contracts "set aside" for small businesses because it did not qualify as a "small business nonmanufacturer." 13 C.F.R. § 121.406(b) (listing four qualifying factors) In particular, Relator claims that Metro Medical was not a "nonmanufacturer" because it did "not take ownership or possession" of Smith & Nephew's products "consistent with industry practice." Dkt. 3 ¶¶ 59-62.

Smith & Nephew's motion to dismiss showed that the Complaint misrepresented the applicable regulations in two respects. First, Relator failed to advise the Court that qualified nonmanufacturers were not required to take ownership or possession of an item until September 2011—which was 8 months after Relator's employment ended at Smith & Nephew. *See Wear Mark, Inc.*, 2012 WL 4359132, at \*6 ("From the initial promulgation of the nonmanufacturer rule in 1958 until the amendment in 2011, a small business nonmanufacturer could qualify for a small business set-aside never having touched or owned the item being procured."). Second, Relator's Complaint wrongly assumed that the 2011 rule change required Metro Medical to take physical possession of an item when, in reality, nonmanufacturers "need not take physical possession to take ownership of an item, if title to the item has passed." *Id.* at \*8.

In response, Relator downplays his errors by specifically alleging that Smith & Nephew personnel *physically delivered* products directly to the Government. Dkt. 37 at 10; *cf.*, Dkt. 3 ¶ 76. But even if Relator's Complaint made that specific allegation—which is a stretch—Relator has

no information about how Metro Medical distributed products to the Government after the 2011 rule came into effect. Regardless, even if Smith & Nephew personnel hypothetically delivered an item to the Government after 2011, that would not somehow “foreclose” Metro Medical from contractually taking title during delivery. Dkt. 37 at 10 (wrongly claiming that Metro Medical could have only obtained title by hiring a common carrier). Relator lacks any information about Metro Medical’s practices after January 2011 (or about any contracts between Smith & Nephew and Metro Medical). Speculative conjecture cannot satisfy Rule 9(b)’s particularity requirement.<sup>2</sup>

### **III. Relator’s Country of Origin Claim Lacks Sufficient Detail Under Rule 9(b)**

Smith & Nephew’s motion to dismiss showed that Relator’s country of origin allegation should also be dismissed because he neither (1) pled particularized details of a fraudulent scheme nor (2) identified specific examples of false claims. Dkt. 18-1 at 16-18. In response, Relator has tried to fill the holes in his Complaint by asserting new facts for the first time in his opposition to the motion to dismiss. For instance, the response cites an unknown “declaration” as the basis for his belief that a certain product was manufactured in Germany. Dkt. 37, at 15 n.9. Similarly, the response includes a “screen shot” of a “contract” that Relator claims provides an example of Metro Medical’s misrepresentations. *Id.* at 15. These new allegations cannot save Relator’s complaint.

First, the Court should not consider the new facts alleged in Relator’s response. *Gomez v. Early Warning Servs.*, 2013 WL 12147021, at \*2 (W.D. Tenn. July 18, 2013) (refusing to “consider the additional facts alleged in [plaintiff’s] response in opposition to . . . motion to dismiss). Second, even if the Court did consider the new “facts,” an unsourced “screen shot” from a “government

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<sup>2</sup> Relator’s response also argues for the first time that Metro Medical was not a “nonmanufacturer” because it did not distribute a product made by a small business. But even if Relator could include that new allegation in his response, the allegation fails because Relator did not plead that Metro Medical failed to obtain a waiver of that requirement. *Cf.*, Dkt. 3 ¶¶ 59-62; *see* 13 C.F.R. § 121.406(b)(1)(iv). Relator has no information about whether Metro Medical obtained waivers when distributing the products at issue; he must plead a basis for that claim to satisfy Rule 9(b).

contract” does not identify an actual false claim (or statement) with specificity. *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 618 F.3d 505, 514 (6th Cir. 2010) (there is no “support for the argument that a contract—even an especially well-identified one—is a ‘claim’ within the meaning of the FCA”); *Bledsoe*, 501 F.3d at 504 (failure to identify with particularity any actual false claims was “fatal”). Relator has failed to allege *any facts* about any instance when Defendants misrepresented a product’s country of origin. Relator’s bare reference to contract summaries he pulled from the internet is insufficient. The country of origin claim fails to state a claim.

#### **IV. Relator’s Conspiracy Allegations Are Deficient**

In 2017, the Sixth Circuit held that in order “to adequately allege an FCA conspiracy, it is not enough for relators to show there was an agreement that made it *likely* there would be a violation of the FCA; they must show an agreement was made *in order to* violate the FCA.” *Ibanez*, 874 F.3d at 917. In response, Relator tries to escape that straightforward holding by citing a 1991 case and then arguing that the recent case only applies when a plaintiff pleads an attenuated scheme. Dkt. 37 at 19. That is incorrect. The *Ibanez* court clearly held that there was “insufficient allegations to show there was a plan to get false claims paid.” *Ibanez*, 874 F.3d at 917. It is not enough to allege facts suggesting “an inference” that there was a plan; the plan must have been designed to submit false claims. *Id.* Without particular factual allegations that Smith & Nephew and Metro Medical intended to defraud the Government, Relator’s conspiracy claim must fail.<sup>3</sup>

#### **V. Conclusion**

For the foregoing reasons, Smith & Nephew asks the Court to grant its Motion to Dismiss.

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<sup>3</sup> The Complaint also fails to allege how Smith & Nephew “caused” Metro Medical to submit false claims. Without specific factual allegations about Smith & Nephew’s actions, Relator’s claim against Smith & Nephew must be dismissed. Nor does the fact that Relator never worked for Metro Medical somehow excuse his failure to plead with particularity. *Chesbrough*, 655 F.3d at 472 (rejecting argument that the particularity requirement should be relaxed when “information about claims submitted to the government is exclusively within [defendant’s] control”).

Dated: March 6, 2018

Respectfully submitted,

/s/ R. Jeffrey Layne

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**CERTIFICATE OF SERVICE**

I hereby certify that on the March 6, 2018, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system and a copy was made available to all electronic filing participants.

/s/ Byron N. Brown

*Counsel for Defendant Smith and Nephew,  
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